

Patented Medicine Prices Review Board: June 2020 Draft Guidelines Consultation

Canadian Cancer Society's Feedback to PMPRB's revised draft guidelines August 4, 2020

The Canadian Cancer Society (CCS) appreciates the opportunity to submit feedback on the June 2020 revised draft guidelines released by the Patented Medicine Prices Review Board (PMPRB).

In our previous submission (February 2020), we expressed our concerns about the impact of the proposed changes on people with cancer. Specifically, we highlighted that the PMPRB should ensure that the proposed changes do not negatively affect patient access to medicines, the future of new treatments or cancer treatment research in Canada. We also emphasized the need for increased transparency and further collaboration with key stakeholders, including patient representative organizations.

While we recognize the June 2020 draft guidelines have been revised and updated since the public consultation (November 2019–February 2020), CCS continues to be concerned about the impact of the guidelines on people with cancer. There are still many questions that remain unanswered in the revised guidelines. CCS would like to use this submission as an opportunity to re-iterate our positions.

About us

The Canadian Cancer Society (CCS) is national community-based organization of volunteers whose mission is the eradication of cancer and the enhancement of the quality of life of people living with cancer. Our vision is to create a world where no Canadian fears cancer. Our collective includes people living with cancer, their families and friends, healthcare teams, donors, researchers, scientists and CCS staff and volunteers. With the help of hundreds of thousands of people that CCS brings together, we are a force-for-life in the face of cancer. As Canada's largest health charity, we fund world-class research, advocate for strong health policy, and help people with cancer and their families by providing evidence-based information on cancer-related issues.

Introduction

Cancer is a disease that can affect anyone; it is estimated that about 1 in 2 Canadians will develop cancer in their lifetimes and 1 in 4 will die of the disease. In 2019, there were an estimated 220,400 new cancer diagnoses and 82,100 deaths from cancer in Canada.¹ With cancer rates projected to increase considerably by 2042, cancer is the single most serious health challenge facing Canada's aging society. During the past two decades, cancer treatment options have significantly improved. Notably, cancer medications have played an essential role to improve health outcomes and quality of life for people living with cancer.

¹ Canadian Cancer Statistics Advisory Committee. Canadian Cancer Statistics 2019. Toronto, ON: Canadian Cancer Society; 2019. Available at: cancer.ca/Canadian-Cancer-Statistics-2019-EN (January 15 [2020]).

Research in cancer treatment

CCS believes it is important to foster a research environment in which cutting edge cancer research is sustainable. Accordingly, as the largest national charitable funder of cancer research, CCS invests in the best research across 100+ types of cancer to give us a valuable sightline on all aspects of the cancer landscape and allows us to translate key learnings from one area of focus to another. In 2018, we invested \$40.4 million in the best cancer research in Canada. These funds supported 304 innovative and influential research projects to help people with cancer live more fully. This investment also included \$4.7 million to support the Canadian Cancer Trials Group, which conducted 122 trials involving 1,547 Canadians at 84 cancer centres across the country. For many people with cancer, clinical trials serve as a treatment option and provide a vital opportunity to increase survival. The revised draft guidelines do not address our concerns about the need to support continued investments in research and we believe, they may represent a threat to those patients who rely on a robust clinical trials infrastructure to support their cancer journey. We would like to work with the PMPRB to ensure that this does not become a reality.

Improvements in scientific research can deliver significant value to healthcare systems, patients and society at large. It is critical for drug discovery research to focus on new targets and tackle cancers with an unmet need. Canada is home to world renowned hospitals, universities and researchers that are conducting strong clinical research. This infrastructure must be supported in order to ensure continued high-quality research and access to the best treatments for people living with cancer.

Oncology is experiencing a significant wave of innovation that is changing the way cancer is diagnosed, treated, and monitored. Advancements in cancer treatment includes gene therapy, immunotherapy, hormone replacement therapy and targeted drug delivery systems. CCS believes in establishing a system, (including the PMPRB), that supports and facilitates the implementation of novel interventions in health practice.

Access to cancer treatments

CCS believes that all Canadians should have access to needed cancer treatments without financial hardship. Having said that, CCS recognizes that the Canadian oncology market has been characterized by significant sales growth and increasing treatment costs in recent years, resulting in issues of affordability and access for patients. Research shows that sales have almost tripled during the past 10 years; In fact, nearly one-third of the growth in pharmaceutical sales in Canada during that time can be attributed to oncology medicines. Treatment costs for oncology medications have also nearly doubled since 2009. The sales-weighted average treatment cost per 28-day cycle has grown from \$4,000 to \$7,600 during the past decade, and medicines with 28-day treatment costs of more than \$10,000 now represent one-third of total sales. These trends are likely to continue based on the predominance of oncology medicines in the pipeline.²

In some respects, this is good news in that oncology medicines play an important role for patients and the emergence of exciting new developments has represented real progress for all those affected by cancer.

² <http://www.pmprb-cepmb.gc.ca/view.asp?ccid=1453&lang=en>

However, it is important too, to make sure that the treatments are priced appropriately. For that reason, CCS strongly supports the PMPRB in its efforts to secure lower prices for medicines, particularly, through comparisons of prices charged in similarly developed countries. However, in light of a lack of data addressing the effects of the PMPRB's proposed reforms, it is critical to take a phased approach to the implementation of the revised guidelines in order to fully understand the impact of these changes. Otherwise, the proposed guidelines could substantially undermine access to medications and the availability of new treatments in Canada.

CCS welcomes the increased pharmacoeconomic thresholds that would be used to guide the determination of an acceptable price for high-cost Category 1 medicines.³ However, CCS remains concerned that without a phased approach to the guidelines, this approach to price-setting may lead to reduced access by years for new cancer medicines for Canadians. Research by IQVIA Canada, a Real World Solutions Consulting Group, reported that Canada launched 70% of new oncology medicines with a 1.1 years median time to launch.⁴ Additionally, among 37 new medicines launched globally in 2018, over half of them were not launched in Canada, with a majority of those being in oncology or rare disease medications.^{Error! Bookmark not defined.} Further research by Life Sciences Ontario suggests significant negative impacts on product launches, commercialization and supply.⁵ It can be extremely difficult for a person living with cancer and their family members to know that a cancer medication may be accessible in the global market, but not available in Canada. More often than not, people living with cancer have a limited amount of time to manage their disease before the disease progresses and are unable to wait for prolonged periods of time for a new treatment to emerge. As such, timely access to treatment is extremely critical to people with cancer.

CCS has also noted that PMPRB staff have broad discretion to modify price tests and thresholds when products are subject to investigation. Based on this, CCS calls on the PMPRB to prioritize patients and recognize the implications of the tests that are being used on people with cancer. In our view, the revised PMPRB guidelines appear to be significantly more complex than the current price review process and will impose substantial new obligations on patentees and PMPRB staff. These new complex rules will require both sides to be adequately resourced to undertake the work associated with the additional requirements. This is another risk for timely access that we are concerned could have very real effects on people with cancer. PMPRB should ensure risk mitigation strategies are in place to protect patients from access-related challenges.

Impact of the recent Federal Court decision

The Federal Court of Canada upheld the new regulations related to obtaining information about price regulatory factors. However, the recent Federal Court decision calls the use of economic factors into

³ Category 1 drugs are very expensive, new, patented drugs that are an effective treatment for a life threatening and/or debilitating disease.

⁴ Life Sciences Ontario. New medicines Launches: Canada in a Global context. Retrieved from https://lifesciencesontario.ca/wp-content/uploads/2020/06/EN_LSO_Global-Launch-Benchmarking_Webinar-June22-20_Final.pdf

⁵ <https://lifesciencesontario.ca/wp-content/uploads/2020/02/Research-Etc.-PMPRB-Survey-02-03-20.pdf>

question. Since the PMPRB will not have any information to assess a patentee's compliance with the Maximum Rebated Price (MRP), it is unclear how the proposed use of economic factors will be applied in practice. CCS calls on the PMPRB to re-clarify the use of economic factors. As stated earlier, this decision further highlights the importance of taking a phased approach in the implementation of the guidelines to properly assess the implications the changes and gather the necessary data to prevent any negative consequences.

Next steps

CCS recognizes the complexity in balancing competing interests. However, the impact on patients must be considered as the highest priority. To achieve the benefits of advanced research, it is important to collaborate between all key stakeholders, particularly patient organizations, to ensure patients remain at the centre of discussion. Accordingly, CCS urges the PMPRB to be transparent about how it intends to generate meaningful stakeholder engagement in the context of its current reform effort. Thus far, none of the key concerns identified by the patient community about the implications of the proposed reforms have been adequately addressed by the PMPRB.

In light of a lack of data demonstrating the full impact of the revised guidelines on patient access to new medicines, CCS calls on the PMPRB to publicly address those concerns through dialogue and data. In the meantime, CCS proposes again that the implementation of the new *Patented Medicines Regulations* be pursued using a phased approach, starting with the application of the updated comparator countries to help achieve affordable prices for patients and health systems. After their impact can be properly assessed, it may be appropriate to reconsider the use of new economic factors. Furthermore, CCS recommends the inclusion of case studies in the guidelines to help all stakeholders better understand how they will be applied in various scenarios in light of the increased complexity of the revised draft.

In conclusion, CCS acknowledges and supports the changes made to the revised draft guidelines this far. However, we need to continue to collaborate in order to ensure that the end result would improve health outcomes for patients. CCS welcomes the prospect of continuing to engage with the PMPRB in an effort to ensure that the reforms support, not hinder people with cancer.